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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,969	12/14/2001	Richard A. Pittner	0401-UTL-0	7314

7590

06/18/2003

ARNOLD AND PORTER
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EXAMINER

LI, RUIXIANG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,969

Applicant(s)

PITNER ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,13-22,24-28 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-12,23,29 and 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

I. Status of Application, Amendments, and/or Claims

The amendment filed in Paper No. 13, on February 19, 2003 has been entered. Claims 1, 6-8, 11, 12, 23, 31, and 32 have been amended. Claims 1-33 are pending and claims 1, 4-12, 23, 29, and 31-33 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

II. Withdrawn Objections and/or Rejections

The rejection of claims 6, 7, 11, 12, 31, and 32 under 35 U.S.C. 103(a) as being unpatentable over Malaisse-Lagae et al. (*Experientia* 33:915-917, 1977) in view of Yoshinaga et al. (*Am. J. Physiol.* 263:G695-701, 1992), Allen et al. (*Digestion* 30:255-262, 1984), and Ueno et al. (*Gastroenterology*, 117:1427-1432, 1999), as set forth in previous Office Action (Paper No. 10, November 15, 2002), has been withdrawn in view of Applicants' amendment to the claims by addition of a limitation of a specific range of dosages.

III. Claim Rejections Under 35 U. S. C. § 112, 1st Paragraph—New Matter

Claims 6, 7, 11, 12, 31, and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains

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subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6, 7, 11, 12, 31, and 32 introduce new matter because the specific ranges of dosages recited in the claims are not supported by the specification. The Examiner fails to find the support for the recited ranges of dosages in Example 7, as Applicants have indicated in the amendment, or in the rest of the specification.

IV. Claim Rejections Under 35 U. S. C. § 103 (a)

The rejection of claims 1, 4, 5, 8-10, 23, 29, and 33 under 35 U.S.C. 103(a) as being unpatentable over Malaisse-Lagae et al. (*Experientia* 33:915-917, 1977) in view of Yoshinaga et al. (*Am. J. Physiol.* 263:G695-701, 1992), Allen et al. (*Digestion* 30:255-262, 1984), and Ueno et al. (*Gastroenterology*, 117:1427-1432, 1999), as set forth in previous office action (Paper No. 10, November 15, 2002), remains.

Applicants argue that the cited references fail to teach each and every limitation of the independent claims and the Examiner has failed to point out any specific teachings that would lead one of ordinary skill in the art to modify the references to arrive at the present invention with a reasonable expectation of success. Specifically, Applicants argue that the references do not disclose or suggest the unexpected ability of PYY and PYY agonists to reduce caloric efficiency.

Applicants' argument has been fully considered, but is not deemed to be persuasive because the claimed invention are drawn to a method of treating obesity or

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reducing food intake, the cited references in combination suggest the same method of treating obesity or reducing food intake comprising administering pancreatic polypeptide (PP), peptide YY (PYY), or PYY agonist. Despite the fact that none of the cited reference teaches the use of PYY and PYY agonists to reduce caloric efficiency, such a property of reducing caloric efficiency is inherent in the used peptides. Discovering a new property of the peptide used in a known method of treatment does not make the method itself novel or not obvious.

Applicants argue that based upon the cited references, one of skill in the art would not have a reasonable expectation of success in substituting PYY for PP in the method of Malaisse-Lagae et al. because there is no suggestion in the cited references that such an effect on secretion of pancreatic exocrine is necessarily linked to an ability to treat obesity, reduce food intake, or reduce nutrient availability, particularly in view of the known differences in activity of various pancreatic polypeptide family members.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, Malaisse-Lagae et al. clearly teach that pancreatic polypeptide (PP) reduces food intake and suppresses body weight gain in the hyperphagic obese mice. Ueno et al. teach decreased food intake and body weight in pancreatic polypeptide-overexpressing mice and the inhibitory effect of PP on pancreatic exocrine secretion (1st paragraph of right column of page 1427). Thus, one of skilled in the art would be convinced that the inhibitory effect of PP on pancreatic exocrine secretion is linked to reduced food intake and suppression of body weight gain.

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Secondly, Yoshinaga et al. teach PYY is structurally similar to PP and that PYY is a potent inhibitor of pancreatic exocrine, gastric acid, and insulin secretion. Therefore, It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute PP for PYY in the method of treating obesity as taught by Malaisse-Lagae et al. with a reasonable expectation of success.

V. Information Disclosure Statement

The references listed in the Information Disclosure Statement submitted by Applicants in Paper No. 12 on 2/19/2003 have been considered. The examiner notes that the Abstract of Okada et al. is considered to be pertinent to applicants' disclosure because Okada et al. teach reduction of food intake by PYY in rats.

VI. Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
June 17, 2003

Gary L. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
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